K 072961

Section 5

510(k) Summary

Contents

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510(k) Summary

LOTUS Ultrasonic System for Cemented Implant eXtraction System (USCIX)

Common Name:	Ultrasonic Surgical Instrument
Classification Name:	Instrument, Surgical, Sonic And Accessory/Attachment
Product Code:	JDX
Subsequent Class:	LZV
Sponsor:	SRA Developments Ltd Bremridge House Ashburton Devon TQ13 7JX UK T: +44 1364 652426 F: +44 1364 653589
Contact:	Dr. Michael J.R. Young,

A. REASON FOR SUBMISSION

This 510(k) is being filed to obtain clearance to market the LOTUS Ultrasonic System for Cemented Implant eXtraction System (USCIX).

B. LEGALLY MARKETED PREDICATE DEVICES

This premarket notification will demonstrate that the LOTUS Ultrasonic System for Cemented Implant eXtraction System (USCIX) is substantially equivalent to the Orthosonics OSCAR OE3000DB cleared by FDA as K051053.

C. DEVICE DESCRIPTION

The USCIX consists of a power module which generates the ultrasonic energy and provides overall control of the device, a reusable implant removal handpiece, a reusable acoustic coupler and a range of single use adaptors. USCIX employs longitudinal mode ultrasound at nominally 29kHz (Range 28.00-30.00kHz) to remove cemented implants for revision.

D. INTENDED USE

The LOTUS Ultrasonic System for Cemented Implant eXtraction System (USCIX) is indicated for the softening of bone cement to facilitate the removal of implants, including pedicle screws and other spinal implants, during revision surgery.

E. TECHNOLOGICAL CHARACTERISTICS

The basic technological characteristics of the USCIX are the same as those of the predicate device. Both systems are designed to use ultrasound to remove an implant from bone cement during revision surgery. The primary difference is that the USCIX system is specifically designed to apply the ultrasound directly to the implant, softening the bone cement encasing it. This approach is particularly advantageous where the access to the bone cement is restricted such as in the spine. The predicate applies the ultrasound to the bone cement via a probe to soften it facilitating the implants removal. The USCIX utilises the same process used by OSCAR when its titanium probe has become accidentally or deliberately embedded in cement. In this case the OSCAR probe is directly equivalent to the USCIX implant (See OSCAR User Manual in **Section 13** of this submission).

F. SUBSTANTIAL EQUIVALENCE SUMMARY

USCIX is a medical device, that uses ultrasound to soften bone cement to facilitate the removal of an implant during revision surgery. This is the same function as the predicate device.

USCIX has the same technological characteristics as the predicate devices. However, the descriptive characteristics may not be sufficiently precise to assure substantial equivalence. Therefore, performance testing was carried out for some characteristics. The data from this testing are available and are presented in this 510(k). The data do in fact demonstrate equivalence.

G. TESTING

Testing to FCC Part 18 has been carried out at EMC Network (SW) Ltd, Devon UK, refer to **Section 17** for data. Electrical testing to UL 60601-1 has been successfully carried out by Underwriters Laboratories and the Certificate of Compliance is included in **Section 17**.

H. CONCLUSIONS

This premarket notification has demonstrated substantial equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2007

SRA Developments, Ltd.
% Michael J.R. Young, Ph.D.
Managing Director
Bremridge House
Asburton, Devon, TQ13 7JX
United Kingdom

Re: K072961
Trade/Device Name: LOTUS Ultrasonic System for Cemented Implant eXtraction System (USCIX)
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic surgical instrument and accessories/attachment
Regulatory Class: II
Product Code: JDX
Dated: October 11, 2007
Received: October 19, 2007

Dear Dr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072961

Device Name: LOTUS Ultrasonic System for Cemented Implant eXtraction System (USCIX)

Indications For Use:

The LOTUS Ultrasonic System for Cemented Implant eXtraction System (USCIX) is indicated for the softening of bone cement to facilitate the removal of implants, including pedicle screws and other spinal implants, during revision surgery.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072961